1. The full name of the patient;

2. The complete name of each drug dispensed;

3. The strength and quantity of the drug dispensed;

4. Instructions as to the frequency of use;

5. The date of dispensing; and

6. The identity of the dispensing practitioner, if more than one practitioner dispenses in the office.

(e) Each different drug dispensed, in whatever dosage form, shall be placed in a separate container with a safety closure cap, unless the patient requests otherwise or the drug is a pharmaceutical sample which has been packaged and labeled by the manufacturer.

(f) Each drug dispensed, including pharmaceutical samples, shall bear a legible label which includes the following:

1. The complete name of the drug dispensed;

2. The strength and quantity of the drug dispensed;

3. Instructions as to the frequency of use;

4. Special precautions, as appropriate; and

5. The expiration date of the drug.

(g) With respect to any drug which is not packaged by the manufacturer as a sample, the label shall also include the following:

1. The full name of the patient;

2. A list of the ingredients if the drug was compounded, not manufactured;

3. The date of dispensing; and

4. The identity of the dispensing practitioner.

(h) A practitioner shall not charge any patient a fee for a drug packaged and labeled by a manufacturer as a sample. For any drug dispensed which is not packaged by the manufacturer as a sample, a practitioner may charge a fee to allow for a recoupment of a portion of overhead and administrative costs, which fee shall not exceed the actual acquisition cost plus an additional sum not to exceed 10 percent of the actual acquisition cost.

(i) Subject to the exception in (j) below, if a practitioner charges a fee for the drug dispensed, either directly or through a global office visit charge which is more than that practitioner's usual and customary visit charge, the practitioner:

1. Shall not dispense that drug or a substantially equivalent drug in a quantity or in dosages greater than that which would allow the patient a seven-day supply;

2. Shall not dispense that medicine or a substantially equivalent medicine at a frequency greater than once every 30 days;

3. Shall assure that information is given to the patient regarding the alternative availability of the drug outside of the practitioner's office; and

4. Shall disclose to the patient in advance of purchase and again on the bill the actual acquisition cost of the drug.

(j) In accordance with N.J.S.A. 45:9–22.11, the requirements set forth at (i) above shall not apply to a practitioner:

1. If the office at which the dispensing occurs is situated 10 or more miles from the nearest licensed pharmacy;

2. If the drug is dispensed pursuant to an oncological or AIDS protocol;

3. If the drug dispensed is a salve, ointment or drops; or

4. If the drug is dispensed in, and directly related to, the services rendered to the patient at:

i. A hospital emergency room;

ii. A student health center at an institution of higher education; or

iii. A publicly subsidized community health center, family planning clinic or prenatal clinic.

(k) The requirements set forth in (d) through (g) above shall not apply to the dispensing of non-prescription substances.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
Rewrote (i)2; inserted (k).

13:35–7.5A Limitations on prescribing, administering or dispensing of drugs for the treatment of obesity

(a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

"Bariatric practice" means the practice of medicine by any physician relating to the treatment of obesity, in conjunction with those co-morbidities affected by obesity.

"Body mass index" means a calculation determined by dividing the measured body weight in kilograms by body height in meters square (kg/m^2).

"Co-morbidities" means any disease, psychiatric or medical condition that may be negatively influenced by obesity, such as diabetes, hypertension, hyperlipidemia, osteoarthritis, cardiac conditions, stroke, respiratory disease and certain cancers.

"Informed consent" means the agreement of the patient to follow the therapeutic regimen established by a practi-

tioner, which follows the disclosure by a practitioner of that information which a patient needs as to available choices with respect to the proposed treatment, including the inherent and potential risks of such treatment.

"Obesity" means a complex, multi-factorial condition characterized by a documented diagnosis of excess adipose tissue as determined by the calculation of a body mass index greater than 27.

(b) A practitioner who engages in bariatric practice shall not prescribe, order, dispense, administer, sell or transfer any drug for the treatment of obesity except in accordance with the provisions of this subchapter and in conformity with the following requirements:

1. A practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, take a complete history of the patient and conduct a comprehensive physical examination and order or perform any laboratory and/or diagnostic tests as indicated by the clinical evaluation. The history, physical examination and laboratory and/or diagnostic tests shall be undertaken in an effort to determine the existence of any co-morbidities and if the use of any prescription medication is contraindicated. The practitioner shall also assess the possible existence of any psychiatric or psychological condition (such as, but not limited to, depression or substance abuse) which shall be evaluated and treated prior to or contemporaneous with the treatment of obesity and which may pose a contraindication to the use of prescription medications. The practitioner shall fully document the findings of the history, physical examination and laboratory and/or diagnostic tests in the patient record and shall also indicate the methods and goals of treatment in the patient record;

2. A practitioner shall provide for nutritional counseling, recommendations for behavior modification and appropriate exercise for weight loss, and document such recommendations in the patient record;

3. A practitioner shall obtain written or verbal informed consent from the patient before prescribing, ordering, dispensing, administering, selling or transferring medication, pursuant to the provisions of this subchapter, for the treatment of obesity. The practitioner shall, either verbally or in writing, identify the risks associated with the use of such medications; and

4. (Reserved)

5. A practitioner shall monitor the progress of the patient's weight loss or gain at the time of each of the patient's follow-up visits. The practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, conduct a physical examination and shall perform laboratory tests as indicated by the clinical evaluation. The findings of the physical examination shall be fully documented in the patient record.

6. (Reserved)

(c) Any violations of this section shall be subject to the enforcement provisions of N.J.A.C. 13:35–7.10.

New Rule, R.2000 d.401, effective October 2, 2000.
See: 31 N.J.R. 2457(a), 32 N.J.R. 3577(a).

13:35–7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

(a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:

1. A recognized medical indication for the use of the controlled substance;

2. The complete name of the controlled substance;

3. The dosage, strength and quantity of the controlled substance; and

4. The instructions as to frequency of use.

(b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30–day supply, whichever is less.

(c) A practitioner may exceed the 120 dosage unit limitation for Schedule II controlled substances in (b) above, if the practitioner follows a treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative.

(d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

1. Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;

2. Shall remain alert to problems associated with physical and psychological dependence; and

3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

(e) If treatment objectives are not being met, the practitioner:

1. Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

2. Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

(f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.

(g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:

1. The medical history and physical examination of the patient;

2. Other evaluations and consultations;

3. Treatment plan objectives;

4. Evidence of informed consent;

5. Treatments and drugs prescribed or provided, as in (a) above;

6. Any agreements with the patient; and

7. Periodic reviews conducted.

13:35–7.7 Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions

(a) A practitioner shall not issue a prescription for a narcotic drug or for a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment."

(b) Unless registered with the New Jersey Department of Health and Senior Services to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21–10 and N.J.A.C. 8:65–11.2, a practitioner shall not dispense or administer a narcotic drug or a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment," except:

1. To relieve acute withdrawal symptoms, provided that:

i. Such treatment shall not exceed 72 hours;

ii. No more than one day's supply of the drug is provided to the patient at a time; and

iii. Arrangements are made for referring the patient to an addiction specialist or a drug treatment program for treatment; or

2. As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
In (a), and (b), inserted references to depressant drugs.

13:35–7.8 Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines

(a) A practitioner shall not prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine designated as a Schedule II controlled substance for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

(b) A practitioner may prescribe, dispense or administer amphetamine or sympathomimetic amine drugs or compounds designated as Schedule II controlled substances, only as follows:

1. For the treatment of the following conditions:

i. Narcolepsy established by recognized diagnostic criteria;

ii. Idiopathic Central Nervous System Hypersomnia established by recognized diagnostic criteria;

iii. Attention Deficit Disorder established by recognized diagnostic criteria;

iv. Drug-induced brain dysfunction;

v. Epilepsy;

vi. Depression shown to be refractory to other therapeutic modalities; and

vii. Senile apathetic behavior;

2. For immediate use in a hospital for acute conditions such as depression associated with illness or surgery;

3. For the differential diagnostic psychiatric evaluation of depression; or

4. For the clinical investigation of the effects of such drugs or compounds in which case, in addition to other requirements of applicable law, prior application therefor

shall have been made to the Board and approval granted before any such investigation is begun.

(c) A practitioner who prescribes, dispenses or administers amphetamines or sympathomimetic amines shall prepare and maintain patient medical records which accurately reflect the utilization of any drug subject to this section, the specific diagnosis, the information upon which the diagnosis is based, including testing and consultations, and the treatment objectives for which the drug is being prescribed.

(d) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name Schedule II drugs which are subject to this section:

Adderall
Amphetamine
Desoxyn
Dexedrine
Dextroamphetamine
Methamphetamine